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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,749	02/22/2002	Bo Johnson	30275-00006	8409

7590 05/21/2004

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,749

Applicant(s)

JOHNSON, BO

Examiner

Jennifer K. Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32 and 37-44 is/are rejected.
- 7) ☒ Claim(s) 38-41 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/16/04; 4/29/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 45-47 are directed to inventions that are independent or distinct from the invention originally elected for the following reasons: the coated article of newly-added claims 45-46 could be made by another method such as coating with the use of a photochemical method. The composition of newly added claim 47 can be used as a laminate instead of applied in coating solution or used in a method of coating a substrate not used to contact fluid or tissues. Additionally, the biocompatible layer of claim 47 is not required to be heparin, as is required by the elected claims.

2. Since applicant has elected Group II, claims 29-32, a method, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 45-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

1. Claims 38-41 and 44 are objected to for being in improper form. These claims are written as "composition" claims, however they depend from the elected method group of claims. This is improper. If Applicant intended these claims to be directed to a coating composition, they should be written in independent form. In this is the case, Examiner will group these composition claims with the other composition claims, which were non-elected in response to the original restriction requirement, and these claims

will be withdrawn from consideration. Otherwise, the claims must be amended to recite "The method of..." as correctly done in newly-added claims 42-43. For the purposes of examination and to expedite prosecution, Examiner has examined these claims as if they were correctly written to be method claims. Therefore, claims 29-32 and 38-44 are examined, below, pending correction of the claims under objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-32 and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In order to overcome the cited prior art in the PCT application, Applicant has amended the claim to require bonding of the hyaluronic acid "without photochemical treatment". This appears to be new matter. Examiner is unable to find, in the originally-filed disclosure, support for this limitation. While some portions of the specification discuss the drawbacks of using harsh chemicals, support for the absence of photochemical treatment has not been found.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 29, 32, 41, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy (US2002/0087123 A1).

Hossainy teaches coating blood-contacting medical device surfaces with heparin and hyaluronic acid (abstract; P25). The hyaluronic acid acts as an adhesion-enhancing substance for the heparin and therefore “bonds” to the substrate. The materials are applied in solution. Adhesion-enhancing substances may be applied as a primer in the method of Hossainy (P26). There is no teaching in Hossainy of photochemical treatment, so the bonding occurs “without photochemical treatment”, as required by the claims.

The substrate of Hossainy may be stainless steel (see, at least, Examples).

6. Claims 29, 30, 32, 41, 42, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al.

Burns et al. teaches coating fibers, substrates, or mesh with a solution of hyaluronic acid and heparin (abstract; col. 2, line 58; col. 3, line 67-col. 4, line 2; col. 9, line 5). The

Art Unit: 1762

hyaluronic acid inherently "bonds" to the substrate as it adheres for later use. There does not appear to be any photochemical treatment in the method of Burns. Burns teaches a pH range which lies completely within the range claimed by Applicant in claims 30 and 42. The substrate of Burns may be polymer fiber, meeting the limitation of claims 41 and 44.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 30-31, 38-40, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al.

Hossainy et al. teach that which is disclosed above, but fails to teach a pH for the coating solutions. It is Examiner's position that selection of a pH would have been within the skill of an ordinary artisan desiring to optimize a coating operation. Heparin and hyaluronic acid will be most stable and will form more adherent coatings at specific pH ranges.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the requirement that the heparin be either a low molecular weight heparin, unfractionated, or higher molecular weight heparin, it is Examiner's position that it would have been obvious to an ordinary artisan to select a heparin from one of the molecular weight ranges. Likewise, the weight ranges required for hyaluronic acid would have been optimized by an ordinary artisan depending on the coating properties, such as viscosity, desired by one of ordinary skill in the art. As outlined above, it is well settled that determination of optimum values of cause effective variables is within the skill of one practicing in the art.

11. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns.

Burns teaches that which is disclosed above, but fails to teach the molecular weight of the heparin or hyaluronic acid. For those reasons outlined above, it is Examiner's

position that selection of optimum variables, such as this, would have been within the skill of an ordinary artisan.

12. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Hossainy or Burns in view of Shah et al. (6,387,450).

The following rejection is provided as an alternative to portions of the 103 rejections, above.

Hossainy and Burns teach that which is disclosed above, but fail to teach the molecular weight of hyaluronic acid.

Shah teaches a method of coating metallic or polymeric medical devices, to be used in contact with physiological fluids, with solutions of hyaluronic acid at molecular weights of about 70,000 to about 6 million Daltons (abstract; col. 1; col. 4, lines 5-15).

Since Hossainy, Burns, and Shah teach coating metallic or polymeric medical devices used in contact with body fluids with solutions of hyaluronic acid and Shah teaches suitable molecular weight ranges for such solutions, Shah would have reasonably suggested the use of hyaluronic acid with the molecular weights outlined in his method.

It would have been obvious to one of ordinary skill in the art to use the teachings of Shah in the method of either Hossainy or Burns with the expectation of successful results since their coating methods, substances, and substrates are similar to Shah's. The range of Shah overlaps that of claim 38 and is within the range of "about 7 million Daltons" as claimed by claim 39.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Shah's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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May 16, 2004